

### REMARKS/ARGUMENTS

Claims 43-68 are active. Claims 48 and 59 have been revised for clarity. Instances of “DFA-III” have been replaced by “DFA III” for consistency of claim terminology. New claims 66-68 find support in the independent claims from which they depend and throughout the specification, for example, at line 6 from the bottom of page 5 of the specification. No new matter has been added. Favorable consideration of this Amendment and allowance of this case are respectfully requested.

### Restriction/Election

The Applicants previously elected with traverse **Group VI**, claims 30-33, directed to a process for purifying DFA III solution. Claims 1, 4-6, 13-26, 29 and 35-42 were withdrawn from consideration. The requirement has been made FINAL. The Applicants respectfully request rejoinder of any claims that cover subject matter encompassed by the nonelected groups depending from or otherwise including all the limitations of an allowed elected claim, upon an indication of allowability for the elected claim, see MPEP 821.04.

### Objection—Claims

Claims 43, 54, and 56 were objected to for various informalities or in the case of claim 56 as depending from a rejected base claim. These objections are now moot.

### Rejection—35 U.S.C. §112, second paragraph

Claims 43-53 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. This rejection is moot in view of the amendment above.

Rejection—35 U.S.C. §103(a)

Claims 43, 45, 47-55 and 57-59 were rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka, JP 49-117688 (English abstract, “AP” or English translation “N”), Uchiyama, U.S. Patent No. 5,057,418 or Tomita (N), and in view of Saito, et al., Biosci. Biotech. Biochem. 64:3121 and Armarego, Purif. Lab. Chem. 4<sup>th</sup> ed., Ch. 1, pages 1-3.

The prior art does not disclose a process for purifying DFA III by contacting a DFA III containing solution prior to solid-liquid (or chromatographic) separation with **powdered activated carbon** having an average particle size of **15 to 200 microns** as required by independent claims 43 and 54. As explained in their prior arguments which are reiterated below, none of the prior art suggests or provides a reasonable expectation of the superior purity obtained by practicing the process of the invention as opposed to some other purification process.

On page 7, lines 10-17 of the OA in the statement of the rejection, the Examiner asserts:

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to have used **any active carbon source** of any DFA III and to purify the composition to the desired degree of purity. . . a variety of techniques are well-established and **routinely optimized** for the purpose of purification including filtration/adsorption with silicates (e.g. diatomaceous/Fuller’s earth), silica, activated carbon, etc.

This position is reiterated in the Examiner’s response to the Applicant’s arguments on page 10, line 14, of the OA where he states “selection of activated carbon is a **mere matter of judicious choice**”.

These arguments ignore that the claimed processes require contacting the DFA III containing solution with the active carbon particles prior to solid-liquid separation and require the selection of powdered activated carbon having a particular average particle size.

As shown by the experimental data of record, use of the prior art steps or use of other types of adsorbents such as granulated carbon do not provide the same results.

As the Supreme Court recently stated, “there must be some *articulated reasoning* with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int’l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (emphasis added)). While the Examiner does state that one would have been motivated to use activated carbon in a purification process, he provides no articulated reasoning why one would have premixed prior to solid-liquid separation, activated carbon with a DFA III containing solution or selected powdered activated carbon having an average particle size ranging from 15 to 200 microns instead of some other absorbent like silica or granulated activated carbon.

Moreover, the prior art provides no direction as to how to “routinely optimize” a purification process to obtain the superior results realized by the claimed processes to provide DFA III with greater clarity and reduced or no odor. In other words, the prior art does not say what process steps to select or what type of absorbent to routinely optimize to achieve these results. As held in *In re Antonie*, 195 USPQ 6, 8-9 (CCPA 1977), there must be evidence in the record that the prior art recognized that particular parameter affected the result. However, there is no teaching in the prior art that performing the contacting step prior to solid-liquid separation or selecting the size of active carbon particles within the range required by the claims are results-effective variables that could have been routinely optimized.

On the other hand, the Applicants have clearly described an essential difference between prior art methods and the invention—the invention uses powdered active carbon, not granular active carbon, see page 5 of the specification. By selecting powdered active carbon,

the inventors discovered a way to remove undesirable odors from purified DFA III that the prior art processes that use granular active carbon could not.

The Applicants reiterate and expand their prior arguments below explaining why the cited prior art does not suggest or provide a reasonable expectation for a process using the powdered activated carbon of the invention.

Tanaka, JP 49-117688 (USPTO English translation), page 5, last line, indicates that filtrate is “adsorbed onto an active carbon column”. Near the bottom of page 7 it states:

This liquid is adsorbed onto an active carbon column (column diameter: 2.5 cm, column height: 45 cm; packed with a mixture of 30 g active carbon and 60 g No. 535 Celite with distilled water.

Tanaka does not disclose pre-treatment (prior to separation of solid and liquid phases as occurs in column chromatography) with activated carbon particles having an average diameter of 15 to 200 microns. This references can provide no motivation for the contacting step between the DFA III containing solution and the active carbon particles prior to solid-liquid separation or for selecting the powdered activated carbon particles required by the invention, nor any reasonable expectation that such a step or selection would have provided any benefit, such as providing a higher purity DFA III lacking the undesirable odors obtained by conventional purification procedures.

Uchiyama, U.S. Patent No. 5,057,418, col. 5, line 24 and Example 1, col. 6, lines 28-29 refer to processing via a column containing active carbon. This reference also does not disclose activated carbon particles having an average diameter of 15 to 200 microns, nor a step involving pre-treatment of the crude DFA III (prior to solid-liquid separation) with these active carbon particles as opposed to processing the crude DFA III through a column.

Tomita, JP 03259090 A (“N”), involves use of “activated charcoal and cerite” to purify DFA III, but is also silent about treatment with activated carbon particles having an average diameter of 15 to 200 microns.

Saito was not relied upon as teaching active carbon treatment.

Armarego, *Common techniques used in purification* is a general reference that teaches many purification techniques, including recrystallization using activated charcoal (decolorizing carbon) on page 12. However, Armarego did not disclose treatment with activated carbon particles having an average diameter of **15 to 200 microns**. Further, there is no suggestion in Armarego to apply this method to pre-treatment of DFA III prior to solid-liquid separation.

The cited art provides no motivation for performing the pretreatment step of contacting a DFA III containing solution with powdered active carbon prior to solid-liquid separation or for selecting “**powdered activated carbon**” having an average particle size of **15 to 200 microns** as required by independent claims 43 and 54 instead of some other type of adsorbent, such as granular activated carbon.

On the other hand, as disclosed on page 5 of the specification and shown in the Examples the claimed process produces a DFA III product superior to those made by prior art purification processes since they lack the undesirable odors of prior art DFA III preparations. This is further shown by the comparative experimental data in the Declaration, otherwise identical crude DFA III preparations purified using the invention, which uses activated carbon particles having an average diameter of 15 to 200 microns, lack odor and had superior transparency, in comparison to DFA III purified by column chromatography using large particles (1,000  $\mu\text{m}$ ) of active carbon or to a control using no active carbon at all.

The Table below, supported by the Declaration filed June 1, 2010, shows the average score for each of Samples A, B and C.

	Color average score of expert panel	Smell average score of expert panel
Sample A (invention; average size of active carbon particles ~35 $\mu\text{m}$ )	2.95	2.80
Sample B (granular active carbon; average size of active carbon particles = 1,000 $\mu\text{m}$ )	2.05	2.20
Sample C (no active carbon)	1.00	1.00

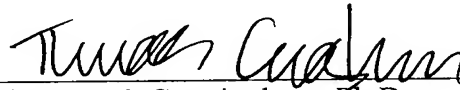
These results demonstrate the superiority of the DFA III product made using the invention. Sample A produced by the method of the invention had a **295%** better color and **280%** better odor in comparison to Sample C which had no active carbon added. Moreover, in comparison to Sample B, which used granular active carbon having an average particle size of 1,000  $\mu\text{m}$ , Sample A had a **144%** better color and **127%** better odor. In addition to the testing results shown in the table above, 19 out of 20 expert panelists rated Sample A as having no color and 16 out of the 20 rated it as having no odor. The prior art does not provide a reasonable expectation of success for DFA III with the superior color and lack of odor provided by the claimed invention. Consequently, for all of the reasons above, this rejection cannot be sustained.

Conclusion

In view of the amendments and remarks above, the Applicants respectfully submit that this application is now in condition for allowance. An early notice to that effect is earnestly solicited.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read "Thomas M. Cunningham", is written over a horizontal line.

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